

### **REMARKS**

This responds to the Office Action mailed on February 8, 2005, and the references cited therewith.

Claims 1 and 4 are amended; claim 2 is canceled; and as a result, claims 1 and 3-5 are now pending in this application.

The specification has been amended to properly recite the priority claim.

Applicants assert that the claims have been amended to properly reflect what is presently claimed. Support for the amendments to claims 1 and 4 is found in the specification on page 11, lines 29-36 and in Example 3. Applicants assert that no new matter is added by the amendments to the claims.

#### **I. The Rejection under 35 U.S.C. §101**

Claims 1-5 were rejected under 35 U.S.C. § 101 because the Examiner states that the claimed invention is directed to non-statutory subject matter. The Examiner states that claims 1-5 are directed to compositions comprising proteins which have the same characteristics and utility as proteins found naturally, and that as such, they do not constitute patentable subject matter. This rejection is respectfully traversed.

On page 3 of the Office Action, the Examiner suggested amending the claims to recite the essential purity of the claimed products to obviate this rejection.

Claim 1 has been amended to recite a composition comprising an amount of an immunologically active purified protein derived from *Borrelia burgdorferi*, wherein the protein is characterized in that it elicits an immunological response from a mammal, has been prepared by expression in a bacterium other than *Borrelia burgdorferi*, is free of other proteins derived from *Borrelia burgdorferi*, and is a protein having SEQ ID NO:11, SEQ ID NO:15, at least 10 amino acids of SEQ ID NO:11, or at least 10 amino acids of SEQ ID NO:15, and a pharmaceutically acceptable carrier, wherein the amount of the protein is effective to immunize a susceptible mammal against infection caused by *Borrelia burgdorferi*.

Claim 4 has been amended to recite a composition comprising an amount of an immunologically active purified protein derived from *Borrelia burgdorferi* wherein the protein is characterized in that it elicits an immunological response from a mammal, has been prepared by

expression in a bacterium other than *Borrelia burgdorferi*, is free of other proteins derived from *Borrelia burgdorferi*, and is a protein having SEQ ID NO:11, SEQ ID NO:15, at least 10 amino acids of SEQ ID NO:11, or at least 10 amino acids of SEQ ID NO:15, and a pharmaceutically acceptable carrier, wherein the amount of the protein is effective to stimulate the formation of antibodies against *Borrelia burgdorferi* in a person.

Thus, claims 1, and 3-5 are amended, pursuant to the Examiner's suggestion, to recite the essential purity and utility of the claimed compositions. Therefore, the withdrawal of the rejection of claims 1 and 3-5 under 35 U.S.C. §101 is appropriate and it respectfully requested.

## **II. The Rejection under 35 U.S.C. §112, first paragraph**

Claim 2 was rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate description or enablement. As Applicants have canceled claim 2, the rejection of this claim under 35 U.S.C. §112, first paragraph, is now moot, and withdrawal of this rejection is respectfully requested.

## **III. The Double Patenting Rejections**

Claims 1-5 were rejected under the judicially created doctrine of double patenting over claims 1-13 of U.S. Patent No. 6,248,538. Additionally, claims 1-5 were rejected under the judicially created doctrine of double patenting over claims 1-5 of U.S. Patent No. 6,183,755.

To advance the prosecution of this application, two terminal disclaimers are enclosed, disclaiming the term of any patent to issue out of this application over the term of commonly assigned U.S. Patent Nos. 6,183,755 and 6,248,538. Withdrawal of these rejections is therefore respectfully requested.

### CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 349-9580 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.


Respectfully submitted,

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By their Representatives,

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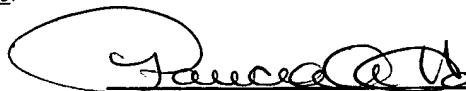
Date 8 August 2005

By   
Patti J. Jurkovich  
Reg. No. 44,813

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8th day of August, 2005.

PATRICIA A. HULTMAN

Name



Signature